REMARKS

Claims 1-24 are currently pending. Claims 1, 11, 22 and 24 have been amended. Support for these amendments is present in the application as originally filed in at least paragraphs [00032], [0036], and FIGS. 1-3.

In view of the above amendments and below remarks it is believed that the pending claims are in a condition for allowance. Reconsideration of the pending claims and an indication of allowance is therefore respectfully requested.

Rejection of the Claims Under 35. U.S.C. § 103

The Combination of Desai and Good or Ponzi Do Not Make Claims 1 and 11 Obvious

Claims 1-3, 5-7, 9-18, and 20-21 stand rejected under 35 U.S.C. 103(a) as being obvious over Desai (U.S. Patent No. 6,461,296) in view of Good (U.S. Patent No. 6,099,457) or Ponzi (U.S. Patent No. 6,540,725). Applicant respectfully traverses this rejection. All of the limitations of independent claims 1 and 11 are not disclosed, taught, or suggested by the proposed combination.

The Office Action states that "Desai fails to disclose the use of a spring-loaded needle." Office Action, May 4, 2007, at 3. The Office Action further states that the use of spring-loaded needles "are old and well known as seen for in Good . . . and Ponzi" *Id.* "The advantage of a spring-loaded needle in the apparatus of Desai would be that it would allow for more efficient and effective actuation of the needle into tissue as taught by Good and Ponzi." *Id.* Neither Good nor Ponzi, however, teach, suggest, or disclose a spring loaded needle as claimed.

Claim 1 of the present application recites a method of "delivering a denervating agent to a prostate gland" that includes "inserting a spring loaded needle encased in a shaft through a perineum of the patient" and "actuating a spring mechanism to cause the distal end of the spring loaded needle to spring bias through a side of the shaft and into the prostate gland." Claim 11 recites a "system for delivering a denervating agent to a prostate gland" that includes "an imaging apparatus sized for insertion through a shaft," a "spring loaded needle for insertion through the shaft," and a "spring mechanism to bias the needle through a side of the shaft and

into the prostate gland upon actuation." Claims 1 and 11 therefore recite a spring loaded needle that uses the force of the spring to penetrate the tissue of the patient through a side of a shaft.

Contrary to the Examiner's assertion, Ponzi does not teach a spring for insertion of a needle. Rather, Ponzi uses the spring attached to the needle for spring loaded retraction of the needle. The spring illustrated in FIG. 2a of Ponzi is described as a "compression spring 88." Col. 9, lines 66-67. In Ponzi,

> force is applied to the piston 84 to cause distal movement of the piston relative to the outer body 80, which compresses the compression spring 88. This movement causes the injection needle 46 to correspondingly move distally relative to the outer body, guide tube 66, protective tube 47 and catheter body 12, so that the distal end of the injection needle extends outside the distal end of the tip electrode 36. When the force is removed from the piston, the compression spring 88 pushes the piston 84 proximally to its original position, thus causing the distal end of the injection needle 46 to retract back into the tip electrode 36.

Col. 10, lines 31-40. Ponzi, therefore, does not disclose, teach, or suggest "actuating a spring mechanism to cause the distal end of the spring loaded needle to spring bias through a side of the shaft and into the prostate gland" as claimed in claim 1 or a "spring mechanism to bias the needle through a side of the shaft and into the prostate gland upon actuation" as claimed in claim 11. Ponzi therefore does not remedy the deficiencies of Desai to make claims 1 and 11 obvious.

Good also fails to remedy the deficiencies of Desai. As referenced by the Examiner, Good discloses a "robotic arm" that "aims a spring-loaded needle injector (which is capable of instantaneously injecting a 21-gauge or 22-gauge thin-diameter needle through human tissues to any desired distance at 1 to 5 millimeters increments to a maximum depth of 40 centimeters) at the target point." Col. 54, lines 40-45. This is the full extent of the disclosure in Good related to a spring loaded needle. At best, Good discloses a spring that linearly injects a needle. Good, therefore, does not disclose, teach, or suggest "actuating a spring mechanism to cause the distal end of the spring loaded needle to spring bias through a side of the shaft and into the prostate gland" as claimed in claim 1 or a "spring mechanism to bias the needle through a side of the shaft and into the prostate gland upon actuation" as claimed in claim 11. Good does not remedy the deficiencies of Desai to make claims 1 and 11 obvious.

The only other reference in Good to a spring is with regards to the "implant gun" of FIG. 20. Col 14, line 40. However, the implant gun as described does not use a spring to inject a needle into the patient. *See* cols. 103-105. Rather, the springs are utilized to selectively block the seeds from traveling out of the seed chamber. *Id.*

Applicants also submit that claims 2-3, 5-7, 9-10, 12-18, and 20-21 are patentable over the cited references based upon at least their dependence from one of claims 1 and 11, each of which are believed to be in condition for allowance for at least the reasons stated above.

In addition, claims 4, 8, and 19, which stand rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Good or Ponzi as applied to claim 1, 7, and 11, and in further view of Henley et al. (U.S. Patent No. 6,477,410), are likewise patentable based upon their dependence from one of claims 1 and 11.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 1-21.

The Combination of Desai in view of Good or Ponzi and Luther Does Not Make Claims 22 and 24 Obvious

Claims 22-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Good or Ponzi and Luther et al. (U.S. Patent No. 7,037,294). Applicant respectfully traverses this rejection on the grounds that no combination of the cited references teach, suggest, or disclose all of the elements of independent claims 22 and 24.

Claim 22 includes limitations to a system for delivery a denervating agent to a prostate gland that includes a spring loaded needle inserted through a transurethral shaft and through a perineum of a patient and "means for spring-biasing the needle into the prostate gland through a side of the shaft." Claim 24 includes a limitation to "actuating a spring mechanism to cause the distal end of the needle to spring bias into the prostate gland at a first location." As explained above, the combination of Desai and Epstein does not teach, suggest, or disclose these limitations.

In addition, amended claim 22 recites that "the spring loaded needle is operably attached to a wheel to permit rotation of the needle while in the shaft to a desired orientation relative to the prostate gland." The spring loaded needle is inserted through a shaft and can be rotated to

deliver denervating agent to multiple prostate locations when spring biased out the side of the shaft. Similarly, amended claim 24 recites "inserting a spring loaded needle through a perineum of the patient, the spring loaded needle extending through a shaft" and repositioning the spring loaded needle by "rotating the needle in the shaft by actuation of a wheel."

The Office Action cites to Luther as disclosing "a needle having a wheel which permits rotation of the needle to a desired orientation." Office Action, at 4. Luther, rather, teaches a hollow needle that can be "rotated by rotating the syringe barrel adapter." However, the needle is not intended to be rotated inside a shaft while inserted in the patient. Rather, "rotation of the hollow needle 120 while the hollow needle 120 is positioned within a patient's vasculature presents the risk of injuring the patient with the rotating beveled tip 122." Luther, col. 4, lines 13-17. When the needle is inserted into the patient Luther allows the "user to rotate the syringe barrel adapter 130 as required for convenience, without simultaneously rotating the hollow needle." Luthere therefore does not cure the deficiencies of Desai, Good, and Ponzi and does not teach, suggest, or disclose the ability to rotate the needle in a shaft while still inserted into the patient.

Claim 23 depends directly from claim 22 and incorporates all of the limitations of claim 2. Claim 23 is therefore allowable for at least those same reasons as presented above.

Double Patenting

Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-12, 15-24 of copending U.S. Patent Application Serial No. 10/698,676. Applicants request that this rejection be held in abeyance until the claims have been indicated as allowable. At that time a terminal disclaimer will be submitted to overcome this rejection.

Conclusion

The Examiner is respectfully requested to contact the undersigned by telephone at 763.505.0409 or by e-mail at scott.a.marks@medtronic.com with any questions or comments.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Respectfully submitted,

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